

Consensus Statement on “Managing the Risks of Repetitive Transcranial Stimulation”

RESOURCE DOCUMENT

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- *APA Operations Manual*.

Preface

In reviewing the consensus statement, the APA Council on Research found the following factors to be especially pertinent. The consensus statement:

1. seeks to deter the unauthorized use of the rTMS procedure by non-medical practitioners;
2. defines rTMS specifically as the administration of a series of magnetic stimuli to the brain for the purpose of altering brain function;
3. specifies that rTMS is an experimental medical intervention under investigation as a potential treatment for neurological and psychiatric disorders;

4. indicates that epileptic seizure is a significant risk of rTMS;
5. provides principles for safe administration of rTMS, as follows:
 - a. rTMS should be administered only by or under orders of a licensed physician
 - b. those who administer the procedure must be trained as “first responders”
 - c. the procedure must be administered in a medical setting
 - d. dosage must be limited by published safety guidelines
 - e. administration must be in compliance with regulations issued by regulator and professional medical organizations.

Each of these considerations was deemed by the Council to be information appropriate for dissemination to APA membership and other mental health constituencies.

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Managing the Risks of Repetitive Transcranial Stimulation

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Repetitive transcranial magnetic stimulation (rTMS), defined as the administration of a series of magnetic stimuli to the brain for the purpose of altering brain function, is an experimental medical intervention. rTMS currently is used to probe various aspects of brain function in the context of research studies approved by local ethics committees. rTMS also is under investigation as a potential treatment for various neurologic and psychiatric disorders. In light of the growing interest in using rTMS in a variety of experimental and therapeutic settings, the International Society for Transcranial Stimulation has recognized the need to formulate a consensus statement to assist the field in developing guidelines for its safe application. Whether the intended use is experimental or therapeutic, certain principles regarding the safety of rTMS apply. This statement is not aimed at guiding the therapeutic use of rTMS in any given condition or its application in any research paradigm, but rather is meant to apply broadly wherever rTMS is used.

rTMS has significant risks, most importantly that of producing epileptic seizures. The degree of risk varies with the dosing parameters and individual subject factors. Therefore, rTMS should be administered only under a licensed physician's orders (ie, by prescription or through some other mechanism that makes a physician directly responsible for its administration to the individual patient or research subject). Because rTMS has potential behavior-changing effects, undesirable side effects, and therapeutic impact, careful assessment of the risk and appropriateness of rTMS in each clinical or scientific context is critical and can only be made by, or in consultation with, a physician knowledgeable and experienced in the use of rTMS and fully trained in neurology, psychiatry, or another appropriate specialty.

rTMS should only be administered under the supervision of an appropriately trained and licensed physician. This does not mean that a physician must be physically present in the laboratory for every study. However, expert medical assistance should be immediately available. A plan for medical supervision should be formed prior to the application of rTMS. This plan should address, but not necessarily be

limited to, the following issues: procedures for screening subjects for risk factors prior to TMS, individual assessment of risks and potential benefits in patients, the informed consent process, setting of rTMS stimulation parameters, and monitoring of subjects during and after rTMS.

Those who administer rTMS should be trained as "first responders" in order to render appropriate care in the event of seizure. rTMS should be performed in a medical setting with appropriate emergency facilities to manage seizures and their consequences. Patients and research subjects should be continuously monitored during the administration of rTMS for signs of epileptic activity or other adverse effects by a trained individual, according to criteria established in the clinical or experimental protocol. This monitoring may include electrophysiologic recording and/or visual inspection. During the informed consent process, patients and study participants should be informed of the risk of seizure and its possible medical and social consequences. The dosage of rTMS should generally be limited by published safety guidelines.¹ If there is a compelling scientific or clinical reason to exceed such guidelines, the rationale for doing so should be considered carefully, documented and the patients or study participants should be informed that they may be at higher risk for seizure.

The long-term risks of rTMS are not known. However, the limited data available at this time from repeated application of high-intensity, time-varying magnetic fields to humans, as in magnetic resonance imaging, do not suggest that they are significant.

The use of rTMS should comply with regulations put forward by local regulatory bodies, medical professional organizations, and medical licensing boards. **CNS**

REFERENCE

1. Wassermann E. Risk and safety of repetitive transcranial magnetic stimulation: report and suggested guidelines from the International Workshop on the Safety of Repetitive Transcranial Magnetic Stimulation, June 5-7, 1996. *Electroencephalogr Clin Neurophysiol.* 1998;108:1-16.

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